Remarks

By the above amendment, claims 1, 2, 6, and 7 have been amended and claims 8-18 are added. The amendments find support throughout the specification and specifically, for example, in paragraphs [0018] and [0030] of the original specification. This amendment adds no new matter.

Interview Summary

Applicants thank the Examiner for the courtesy extended to Applicants' representative, Sean Myers-Payne, in a personal interview conducted on October 5, 2009.

During the interview, Applicants' representative addressed the Examiner's questions regarding public use or sale of the claimed invention. Applicants' representative explained that financial records relating to Eril™ (which had been requested by the Examiner) could not be provided, but that information relating to the public use or sale of Eril™ could be provided. In particular, Applicants' representative provided information relating to the sales of Eril™ in Japan in 2003, including detailed information relating to the specific details of the Eril™ product that was sold. Applicants' representative provided to the Examiner three documents – all written in Japanese – and noted that verified translations were being prepared and would be provided in a formal Information Disclosure Statement. (Such IDS is being filed concurrently herewith and includes both the Japanese language documents provided during the interview as well as full or partial English language translations of relevant portions.) Applicants' representative explained to the Examiner that the documents would show that Eril™ had a pH of 5.7-6.3.

Applicants' representative asserted that the rejection under 35 U.S.C. § 112, first paragraph (relating to physiological effects caused by injection of a low-pH solution), appeared to be inapplicable because the claims were directed to maintaining the stability of a solution of fasudil, not to injecting the solution. While the Examiner agreed with respect to claims 1-3 and 5-7, she maintained that claim 4 specifically mentioned intravascular injection, and thus specifically implicated the actual injection of the preparation. While not necessarily agreeing with the Examiner's position, Applicants' representative noted that the objectionable elements of claim 4 could be construed as statements of intended use, and accordingly, might be considered

not to further limit the claim. Based on this understanding, Applicants' representative discussed with the Examiner the possibility of canceling claim 4.

Finally, Applicants' representative asserted that The Merck Index (the only art cited in the action) did not appear to disclose or suggest a pH of less than 5 and that the present specification supported such range (in, for example, paragraph [0030] of the original specification). Upon further review of the specification after the interview, Applicants' representative recognized that the present specification also provided support for a pH of less than 5.0 (in, for example, paragraph [0018] of the original specification).

While no agreement was reached during the interview, the Examiner agreed to reconsider the rejections of record in view of Applicants' submission of IDS materials and amendments.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Action rejects claims 1-7 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. In response, as discussed above in the Interview Summary section, Applicants have discussed this rejection with the Examiner and submit that the cancellation of claim 4 addresses any remaining issues.

Applicants respectfully request withdrawal of the rejection.

Claim Rejections – 35 U.S.C. § 102

The Action rejects claims 1-7 under 35 U.S.C. § 102(b) based on public use or sale of the invention. As discussed above, Applicants file concurrently herewith an Information Disclosure Statement including information relating to the sale of Eril™ in 2003. While Applicants note that the public use and/or sale of Eril™ was not in the U.S., and thus does not fall within the scope of 35 U.S.C. § 102(b), publications were available in 2003 that disclose the details of the Eril™ product. As can be seen from the publications submitted in the IDS, Eril™ had a pH of 5.7-6.3, and thus, such publications do not disclose the presently claimed invention.

The Action also mentions The Merck Index, 12th Edition, which apparently discloses fasudil having a particular solubility in water at a pH of 5.0-7.0. Applicants submit that The Merck Index does not anticipate the presently claimed invention.

While no rejection under 35 U.S.C. § 103 has been made, Applicants take the opportunity to note that The Merck Index fails to suggest any other pH – indeed, it is merely an informational abstract relating to fasudil, and contains no information about any utility relating to pH. Thus, it does not suggest Applicants' claimed invention.

Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 102.

Conclusion

In view of the foregoing remarks and amendments, Applicants respectfully submit that the claims are in condition for allowance. If there should be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully Submitted,
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